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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,529

08/11/2006

David Dakin Iorwerth Wright

07588.0079

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12/15/2009

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EXAMINER

MOULTON, ELIZABETH ROSE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

12/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,529	Applicant(s) WRIGHT ET AL.	
	Examiner ELIZABETH R. MOULTON	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,10-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,10-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 6, 7 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al (WO 00/72821, provided by applicant).

Osman et al teaches (FIG 2) a sclerosant agent foam made by combining polidcanol and oxygen or carbon dioxide gas through a micropore filter of 0.1 to 30 microns (see Pg 9 and example 3, starting at page 25). Osman shows the agent and gas are mixed (at 9/10) prior to passing through the foaming element (8).

Osman's device is comprised of a housing (1); a first chamber (4), a second chamber (22, volume decreases as foil bag contracts) with sclerosant agent (3); an outlet (13) and a flow path (generally 10) comprising a mixing region (upstream of 11a/11b); and a foaming unit (8) with pores of 0.1-100 microns (Osman discloses 20 micron pores).

Although Osman et al. do not teach the specific amount of nitrogen present in the foam, it would have been obvious to make a foam using the instant amount of gaseous nitrogen (i.e. 0.0001% to 0.8%) because Osman et al. suggest that nitrogen may be absent or present in minor proportions (see column 9 lines 1-5). Thus, one of ordinary skill can reasonably assume that since carbon dioxide can be present up to 90%, that

the composition can comprise between 0% and 10% of nitrogen and other physiologically acceptable gases, which would fall within the range instantly claimed.

Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

As to claims 2-9 and 15 see page 22 line 11-14. As to claims 20, 21 see example 3. As to claim 16, see page 10, line 11. As to claim 22, page 9, line 23. As to claim 23, see pg 7 line 23.

Claims 17-19: Osman teaches adding glycerol in an amount of 10% vol/vol (page 41 claim 62). This amount is selected based on the factors of increasing half-life of the foam and controlling the density of the foam (page 22 line 25-end). Applicant recognizes that the addition of glycerol has the same effects on the foam and evaluated different concentrations of glycerol (see table 16, page 95 and pages 93-95). The concentration of glycerol is clearly recognized as a result-effective variable by both the prior art and the applicant. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a concentration of 20% vol/vol glycerol in order to achieve a desired half-life/foam density combination.

As to claim 14, it is well known in the art to provide a canister in a sterile bag for storage and shipping. The sterile bag would encompass the entire canister, and inside the sterile bag (now the housing) there would be first and second chambers as described above. It would have been obvious to one of ordinary skill in the art at the time the invention was made provide the system in a sterilized bag to prevent contamination before use.

3. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al in view of Gravagna et al (US 6,605,066)

Osman et al teaches (FIG 2) the foam dispenser as described above. Osman does not teach that the agent and gas are held in syringes with plungers.

Gravagna teaches a method of dispensing a foam comprising first and second syringes with plungers to adjust the volume of the syringes. The two foaming agents pass through a mixing chamber (7) before being dispensed as a foam. One syringe may hold a gas (Col 3 line 62). Since it is known in the art to provide a sclerosant and a gas in separate syringe barrels, and to combine them using a mixing chamber, it would have been obvious to substitute two syringe barrels for the two canisters of Osman.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the syringe dispenser of Gravagna to make the sclerosant foam of Osman since Gravagna's device is easily controlled and safe to use (Col 1-2).

As to claims 10 and 11, see Gravagna Fig 1, the motive power 4 pushes the syringe plungers. As to claims 12 and 13, see Gravagna Fig 3. The ratio of the volume of the first syringe is 3:1 to 10:1 the volume of the second syringe (Col 3 line 10-15).

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on part-time R and F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767